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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,651	12/06/2001	Harry R. Howard JR.	PC11839A	4848

23913 7590 10/22/2003

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EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/22/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/010,651

Applicant(s)
Howard, Jr.

Examiner
Deepak Rao

Art Unit
1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 25, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 ☒ are pending in the application.
- 4a) Of the above, claim(s) 1-21, 24, and 29 ☒ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 23, 25-28, and 30 ☒ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-30 are pending in this application.

Election/Restriction

Applicant's election with traverse of Group III, claims 22-23, 25-28 and 30 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the restriction between Groups III and IV is improper because the claims include all compounds having SRI antidepressant activity. This is not found persuasive because the instantly claimed SRI antidepressants include compounds of various different structural features, all of which are differently classified and therefore, require separate and burdensome search in both patent databases and the literature. See e.g., U.S. Patent 5,320,825 lists compounds having SRI activity (Table 1) having diverse structural features, all of which are different from compounds of formula I. Thus, complete search of all of the compounds having SRI activity involves review of thousands of patent documents and references of the literature which is unduly extensive and burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-21, 24 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

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Applicant's election of the species of (a) [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methylamine as the SRI antidepressant and (b) ziprasidone as the atypical antipsychotic compound is acknowledged.

Applicant is reminded of the election of species guidelines provided in MPEP § 803.02, which are followed for examination. Portion from MPEP is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, **a second action on the merits on the elected claims would be final.**

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

The elected species were found in the prior art search and as per the guidelines above, the examination was limited to the elected species. All other SRI antidepressant and atypical antipsychotic compounds of claims 22-23, 25-28 and 30 are withdrawn from further

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consideration by the examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected species.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Claim 23 depends from itself. As indicated in the previous office action, the claims were renumbered according 37 CFR 1.126, however, the dependency of the claims was not adjusted. Appropriate correction of the dependency is suggested.
2. Regarding claim 23, the phrase "i.e." (see page 30, line 28) renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-23, 25-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott et al., WO 00/50380 and Busch et al., WO 97/42190 or Urban, U.S. Patent No. 5,359,068.

Elliott (WO'380) teaches the use of [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methylamine for the treatment of depression, anxiety disorders, obsessive disorders, etc., see the compound at page 7, line 33 and the therapeutic use in page 3, lines 11-32.

Elliott reference does not teach the combination of atypical antipsychotic agent ziprasidone with the SRI antidepressant [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methylamine.

Busch (WO'190) teaches the use of the antipsychotic agent Ziprasidone for the treatment of various disorders including anxiety, see page 1, lines 12-13. Also, Urban (US'068) discloses ziprasidone (see Example 8) and the therapeutic use in treating anxiety, see col. 11.

One of ordinary skill in the art would have been motivated to combine the reference teachings by selecting the two compounds independently taught in the references in a single therapeutic administration because the skilled artisan would have expected the combination to have the same properties and activity taught for the individual compounds as both the compounds are taught to exhibit similar properties. [T]he idea of combining the references flows

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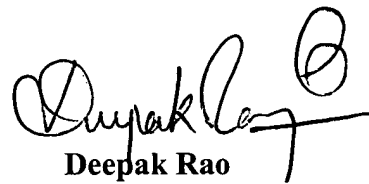
logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
Primary Examiner
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October 20, 2003